

REMARKS

Claims 1-13, 17, and 24 were canceled earlier due to restrictions imposed by the Examiner and required to be withdrawn from consideration. Claim 31 is amended to make it read better. No new matter is included. New claim 32 is added to specify that the multilaminar tie layer has at least two layers of different materials. Support for the amendment can be found, for example, in the drawings. New claim 33 is added to specify that the backing construction is a backing in a transdermal drug delivery system having a primary drug reservoir having a primary drug and that the secondary drug-containing reservoir layer contains a secondary drug different from the primary drug. Support for the amendment can be found, for example, in the drawings and in paragraph [00048]. New claim 34 is added to specify that the backing construction is a backing in a transdermal drug delivery system having a primary drug reservoir having a primary drug and that the secondary drug-containing reservoir layer contains an antagonist of the primary drug. Support for the amendment can be found, for example, in the drawings and in paragraph [00048] and paragraph [00028]. New claim 35 is added to specify a transdermal device having primary drug reservoir and a backing construction with a secondary drug-containing reservoir layer that contains a secondary drug different from the primary drug. Support for the amendment can be found, for example, in the drawings and in paragraph [00048]. New claim 36 is added to specify a transdermal device having primary drug reservoir with a first drug and a backing construction with a secondary drug-containing reservoir layer that contains an antagonist to the first drug. Support for the amendment can be found, for example, in the drawings and in paragraph [00048] and paragraph [00028]. No new matter is added in the amendment or the new claims. Thus, claims 14-16, 18-23, and 25-36 are pending.

Telephone Interview

Applicant notes with appreciation the courtesy extended by the Examiner to Applicant's attorney, Philip Yip, in the telephone interview of June 19, 2007. During the telephone interview, the claim objection on obviousness type double patenting and the Kydonieus reference and the FR2249148 reference were discussed. Philip Yip argued that the Kydonieus device is not a backing and FR2249148 is about only adhesive tapes. No agreement on claim allowance was arrived at.

Double Patenting

The Examiner rejected claims 14-16, 18-23, 25-30 as provisionally rejected on the ground of nonstatutory obviousness-type double patenting over claims 1-9, 13, 21, 43, 54-57, 66, 90-92, 97-99 of copending Application No. 10/420.428 in view of Steinborn et al. US6080421. Applicant respectfully traverses the rejection.

It is submitted that although copending Application No. 10/420.428 and the Steinborn et al. patent are about transdermal drug delivery system, neither of them have a multilaminate tie layer between a top layer and a barrier base layer. According to the Webster's Ninth Collegiate Dictionary (Merriam Webster 1989), "laminating" means "to make by uniting superposed layers of one or more materials". Thus, a "multilaminate" must include at least two distinct layers together. Absent the teaching of the present invention, a person skilled in the art will not think of combining the cited references to arrive at the present invention, which has a tie layer that is multilaminate.

Further, both cited references are about transdermal drug delivery systems, not backings. Neither of them talks about having a backing that contains a drug.

Withdrawal of the objection is requested.

35USC §103(a) rejection

Claims 14, 15, 18-23, 25, 26, 28, and 30 25 were rejected under as being unpatenable over kydonieus et al. (US4758434) in view of Steinborn et al. (US6080421). Applicant respectfully traverses the rejection.

It is submitted that the Kydonieus devices are transdermal drug delivery systems, not backings. The backing on the Kydonieus devices is a single layer (e.g., numeral 6 in Fig. 1), which Kydonieus said is “such as one made of plastic, moisture-proof fabric, aluminum foil, etc.” The backing is shown as a single layer in the drawing and there is no indication of the backing having a multilayered construction, much less a multilayered construction with a multilaminar tie layer having a drug reservoir. Further, the Kydonieus backing is not embossed. Similarly, the Steinborn device is also a transdermal drug delivery system, not a backing. Although Steinborn shows a backing having two layers, the backing does not have a multilaminar tie layer. As pointed out above, a multilaminar tie layer must have two separate distinct layers. There is no such multilaminar tie layer in either references. Thus, even if one assumes that a person skilled in the art would want to try to combine Kydonieus and Steinborn, such a combination will not result in a multilaminar tie layer. Further, such a combination will only result in a drug delivery system to be used directly on skin, not result in a backing that is to be placed in a more complex drug delivery system.

Regarding claim 15, the Examiner asserted that in the absence of compositions for the component layers in the tie layer, the component layers are indistinguishable and therefore the single tie layer of Kydonieus’s embodiment of Fig. 4 reads on the instantly claimed component layers. However, as pointed above, one skilled in the art will know that a multilaminar must have more than one layer. Every element of a claim has to be considered in the analysis of obviousness. A single tie layer cannot read on a multilaminar tie layer. Additionally, Applicant has added new claim 32 specifying that the tie layer has at least two layers of different materials.

The Examiner rejected claims 20 and 26, asserting that the antagonist read on Kydonieus's drug in the drug reservoir. However, Kydonieus's drug reservoir is a reservoir for delivery of a drug to the skin. On the contrary, the antagonist in the present invention is in the backing and is not to be delivered to the patient. The antagonist is only released when our drug device is subject to abuse. There is nothing to prevent the Kydonieus reservoir from delivering the "drug=antagonist" in the drug reservoir to the skin as delivery from the reservoir is intended by Kydonieus. This mode of delivery flies in the face of the present invention. Moreover, the antagonist as used in the present invention is an antagonist to a drug in the primary drug reservoir. Thus the two drugs have countering action and are not to come into contact unless the device is being abused. Thus, the Kydonieus drug reservoir should not render obvious what we have in the secondary drug reservoir.

The Examiner rejected claim 16 as being unpatentable over Kydonieus et al. in view of Steinborn et al. and FR 2249148. The Examiner asserted that FR'148 discloses that an adhesive tape of PET film having non-tacky hot melt EVA coating on both sides is used to join two surfaces and forms a bond by heat treatment and therefore it would be obvious to put the FR'148 tape between the backing and the reservoir to improve adhesion between the layers and improve backing strength. However, the FR'148 device is only an adhesive tape and totally unrelated to transdermal delivery. There is nothing in Kydonieus that suggests a tie layer should be inserted into the backing. It is noted that thick transdermal devices are undesirable as they are cumbersome and unsightly. Who would want a thick ugly patch sticking up from on his skin, catching on his clothing, etc.? There has to be a good reason why a person would want to insert an additional multilayered adhesive tape into a transdermal device. The references never mentioned anything about needing more adhesiveness between the layers or requiring better strength in the transdermal patch. There is no suggestion or mention of a willingness to sacrifice a thin profile for such allegedly better strength or adhesiveness between layers. One would not randomly just insert some extra material into a transdermal device. Whatever motivation there is must be only hindsight gleaned from the present disclosure. Without the teaching of the present disclosure, a person skilled in the art will not think of having a multilaminar tie layer between the top layer and the bottom layer in a backing. Even if assuming one would want to combine the references, the adhesive tape will only be inserted into the transdermal drug delivery device under the backing, not in the mid of a backing construction.

The Examiner rejected claims 27 and 29 by asserting that Kydonieus discloses that the backing layer 34 can be made of aluminum foil which is inherently impermeable to drugs. However, the Kydonieus backing is a single layer on the very top of the Kydonieus device and if it is made with aluminum it cannot be the base layer in a backing layer underneath a secondary drug reservoir layer, as claimed by the claims. There is no indication that the Kydonieus backing is a multilayered structure, much less one with a secondary drug containing layer.

Because of the foregoing reasons, the cited references do not render the present invention obvious. Withdrawal of the rejections is respectfully requested.

CONCLUSION

Applicant submits the pending claims are novel and nonobvious over prior art and comply with the requirements of 35 USC §102 and §112. The examination and passage to allowance of the pending claims are respectfully requested. An early Notice of Allowance is therefore earnestly solicited. Applicant invites the Examiner to contact the undersigned at (650) 564-7054 to clarify any unresolved issues raised by this response.

The Commissioner is hereby authorized to charge any additional fees associated with this paper or during the pendency of this application, or credit any overpayment, to Deposit Account No. 10-0750.

Respectfully submitted,

Dated: June 26, 2007



Philip Yip
Registration No. 37,265
Attorney for Applicant
Customer No. 27777

ALZA Corporation
c/o Johnson & Johnson
One Johnson & Johnson Plaza, WH 3221
New Brunswick, NJ 08933
Phone: 650-564-7054
Fax: 650-564-2195